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10/562,421

05/17/2006

Jan Clair Nielsen

NIELSEN6A

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EXAMINER

GANGLE, BRIAN J

ART UNIT

PAPER NUMBER

1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,421	<b>Applicant(s)</b> NIELSEN, JAN CLAIR	
	<b>Examiner</b> Brian J. Gangle	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4, 6-9, 11, 15, 43, 45, 48-49, and 101-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,6-9,11,15,16,18-20,22-26,29,31,32,34,35,37,38,40-43,45,48-52,55,58,59,63-66,68-76,79-82,84-88,90-95 and 98-103.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 16,18-20,22-26,29,31,32,34,35,37,38,40-42,50-52,55,58,59,63-66,68-76,79-82,84-88,90-95 and 98-100.

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**DETAILED ACTION**

Applicant's amendment and remarks, filed on 5/4/2009, are acknowledged. Claims 13-14 are cancelled. Claims 1, 4, 6-8, 31, 34, 37-38, 74, and 99 are amended. New claims 101-103 are added. Claims 1-2, 4, 6-9, 11, 15-16, 18-20, 22-26, 29, 31-32, 34-35, 37-38, 40-43, 45, 48-52, 55, 58-59, 63-66, 68-76, 79-82, 84-88, 90-95, and 98-103 are pending. Claims 16, 18-20, 22-26, 29, 31-32, 34-35, 37-38, 40-42, 50-52, 55, 58-59, 63-66, 68-76, 79-82, 84-88, 90-95, and 98-100 are withdrawn as being drawn to nonelected inventions. Claims 1-2, 4, 6-9, 11, 15, 43, 45, 48-49, and 101-103 are currently under examination.

***Election/Restrictions***

Applicant continues to argue the restriction requirement set forth on 6/23/2008.

**Applicant argues:**

1. That "a claim which is not anticipated can still be obvious and thereby lack a special technical feature." Applicant states that all the restriction asserted concerning Viljakainen, as basis for a lack of unity, was that the reference discloses multiple species of bacterial that are capable of malolactic fermentation. Applicant argues that this is only one of the requirements of claim 1 and that the restriction requirement does not address the other limitations of the claim.

2. That the examiner did not specify whether the holding was based on anticipation or obviousness and that the examiner should have explained how Viljakainen suggested the non-anticipated features if the claim was not anticipated. Applicant argues that they have pointed out why Viljakainen did not anticipate and thus it is incumbent on the examiner to justify the lack of unity holding by an obviousness argument. Applicant argues that, instead, the examiner has not made an obviousness rejection and states simply that the only feature linking all the groups is the feature that is disclosed by Viljakainen. Applicant asserts that all claims are dependent, directly or indirectly, on claim 1 and thus are all linked by all of the features of claim 1, not just the malolactic fermentation feature.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, applicant correctly states that "a claim which is not anticipated can still be obvious and thereby lack a special technical feature." However, whether or not a *claim* is anticipated or obvious is not the standard for determining unity. According to PCT Rule

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13.2, "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in **Rule 13.1** shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Note that the inventions must share a technical feature. It is whether or not this shared technical feature defines a contribution over the art that determines lack of unity, not whether claim 1 is anticipated or made obvious. There is only one feature that links all of the inventions found in this application, and that is a microbial organism that is capable of fermenting at least one fermentable compound. Since there is nothing more that links the inventions, nothing more must be disclosed by the prior art to break unity. The other limitations of claim 1 are not relevant to a discussion of unity because *they are not shared by all of the claimed inventions*.

Regarding argument 2, discussions of anticipation versus obviousness are inappropriate with regard to determination of unity, as these terms apply to rejections under 35 USC 102 and 103, not to whether or not a technical feature makes a contribution over the art. The determination of whether a technical feature makes a contribution over the art is considered with respect to novelty and inventive step. Clearly, if Viljakainen "discloses" the feature, then that feature is not novel; there is no need to use the word "anticipate." With regard to applicant's assertion that all of the claims are dependent on claim 1 and thus are linked by all of the features of claim 1, applicant is clearly incorrect. As stated previously, the only feature that is shared by all of the claims is a microbial organism that is capable of fermenting at least one fermentable compound.

Applicant is reminded that the restriction requirement has been made FINAL.

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### ***Objections Withdrawn***

The objection to the drawings, as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 11-14, is withdrawn in light of applicant's amendment to the specification.

The objection to claim because each claim should end with a period, is withdrawn in light of applicant's amendment thereto.

### ***Objections Maintained***

The objection to the specification for the use of the trademark TWEEN is maintained for the reasons set forth in the previous office action.

Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant's amendment to include the generic term "detergent" is noted. However, this term insufficiently describes TWEEN, as there are numerous detergents with widely varying characteristics. It is suggested that applicant consult the MSDS sheet for TWEEN 80 to determine an appropriate generic description.

### ***New Claim Objections***

Claims 1 and 101-103 are objected to because of the following informalities: claim 1 refers to "adaption". Claims 101-103 refer to "adaptation." Whichever form applicant wishes to use is fine, but applicant should be consistent and use the same form for all of the claims. Appropriate correction is required.

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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***Claim Rejections Withdrawn***

The rejection of claim 15 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (biological deposit rejection), is withdrawn in light of applicant's remarks regarding the availability of the biological deposit.

The rejection of claims 4 and 6-7, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of applicant's amendment thereto.

The rejection of claims 13-15, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn. Claims 13-14 have been cancelled, thus the rejection of these claims is moot. The rejection of claim 15 is withdrawn in light of applicant's amendment to claim 1 and remarks.

***Claim Rejections Maintained***

***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4, 6-9, 11, 43, 45, 48-49, and newly submitted claims 101-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the rejection of claims 1-2, 4, 6-9, 11, 13-15, 43, 45, and 48-49 in the previous office action. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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**Applicant argues:**

1. That strains DSM 15569, 15570, and 15571 are representative of the claimed genus. Applicant argues that claim 1 is limited to organisms of the genera *Lactobacillus*, *Pediococcus*, and *Oenococcus* (of which, three strains having the claimed characteristics are disclosed), and that, since these are all capable of malolactic fermentation, there is *prima facie* basis for expecting that it is possible to isolate other strains of these genera which have the claimed characteristics.

2. That the examiner cites Eli Lilly, Amgen, and Fiddes as basis for requiring disclosure of the sequence of a nucleic acid or protein. Applicant argues that these cases are related to claims to nucleic acids or proteins and that the instant claims are to organisms of a class which performs malolactic fermentation. Applicant also argues that these cases do not require that every invention be described in the same way and that the PTO has been granting patents on new microorganisms since well before DNA sequencing methods were developed (and thus before there was knowledge of specific sequence-activity correlations).

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, applicant is admitting that the only portion of the invention that has been reduced to practice are the strains DSM 15569, 15570, and 15571. Applicant's arguments show that they have not described any other strain with the required characteristics, but instead have only described a method for obtaining such strains. As stated previously, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Applicant has asserted that the "description" of these strains is sufficient to provide written description for the claimed genus. However, these strains were obtained by randomly mutating *Oenococcus oeni*. Applicant has provided no information whatsoever regarding the nature of the mutations or the structural characteristics of these strains that give rise to their functional characteristics. The genus encompassed by the claims is enormous since it is the number of mutations that could arise within the claimed genera that defines the genus, not simply the number of species within said genera. The specification provides no guidance whatsoever with regard to what mutations lead to the desired characteristics. The strains DSM 15569, 15570, and 15571 are described not by any structural information, but rather are described only by virtue of the biological deposit of said strains. The



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written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Applicant has provided no correlation between any structure and any function and thus has not described any feature common to the genus that would allow one to believe that the deposited strains are representative of the claimed genus.

Regarding argument 2, applicant correctly points out that the cited cases are related to claims drawn to nucleic acids or proteins and that the PTO has been granting patents on microorganisms since before DNA sequencing methods were developed. Whether or not the PTO has issued cases to microorganisms in the past is not relevant to the instant case, as it is the laws that are currently in place that govern the instant case. While the cited cases are directly related to nucleic acids and proteins, the legal principles discussed are not limited to nucleic acids and proteins. Furthermore, while applicant is claiming an organism, the fact is that the claimed characteristics of said organism are obtained through mutation of known organisms. Applicant is taking known and disclosed bacteria and altering their nucleic acids so that said bacteria will have new characteristics. It is the structure of these nucleic acids that leads to the claimed functions. Therefore, the principles discussed in the cited cases are relevant to the instant case. With the exception of the deposited organisms, which are described not by any structural information, but rather only by virtue of the biological deposit, applicant has described their invention using functional characteristics alone. These characteristics have not been correlated in any way to any known structure. As set forth by the courts, functional description alone is insufficient to satisfy the written description requirement. In *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06, the court stated "The present count is to a product, a DNA which codes for b-IF; it is a claim to a product having a particular biological activity or function, and in *Amgen*, we held that such a product is not conceived until one can define it other than by its biological activity or function." While the case was specifically dealing with DNA, the court

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stated that a *product* is not conceived until one can define it by other than its biological activity or function.

Applicant has agreed that the strains DSM 15569, 15570, and 15571 are the only strains described as meeting the limitations of the claims. Applicant has not described any other microbial organism which does so, but has instead described a method for obtaining other strains which meet the limitations. As the strains were obtained by randomly mutating known organisms and selecting those organisms with the desired characteristics, there is no predictable relationship between the strains DSM 15569, 15570, and 15571 and any other organism.

As outlined previously, the instant claims are drawn to an isolated and purified microbial organism that is capable of fermenting malic acid to lactic acid, and which, when placed in a medium containing 1-5000 mg/L of citric acid is only capable of degrading at the most 80% or said citric acid. Said organisms must be capable, under suitable conditions, of adaptation to, when said microbial organism in a frozen or freeze dried state is added directly into a fermented fruit juice: i) a survival rate which is at least 1% after two days at 23° C in a fermented sterile fruit juice with a pH of less than 4 and comprising at least 12 vol % ethanol; ii) a survival rate which is at least 70% after two days at 17° C in a fermented sterile fruit juice with a pH of less than 4 comprising at least 13.9 vol % ethanol.

The specification discloses a list of bacteria that can be mutagenized and then selected in order to obtain a strain that meets the limitations of the claims. Strains DSM 15569, 15570, and 15571 are described as meeting the limitations of the claims. Applicant has not described any other microbial organism which does so. However, there is no correlation between the required function (i.e. the required characteristics) and the structure of the product (the microbial organism). Applicant has not described what organisms would have the characteristics required by the claims.

Therefore, the specification provides insufficient written description to support the genus encompassed by the claim. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

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Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid and/or protein itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

*University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

All applicant has provided in the specification is a means for isolating the organism of the claims, and there is no description of an actual organism that meets the limitations. Because possession of the invention, rather than a means for obtaining it is required, the claims do not meet the written description requirements.

Therefore, applicant has not demonstrated possession of the claimed genus of microbial organisms and has not shown any organism (with the exception of strains DSM 15569, 15570, and 15571) that meets the limitations of the claims.

### ***New Claim Rejections***

#### ***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 8 to recite "malic acid in the range of 1-50 mg/L." This phrase does not appear in the specification or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore, this limitation is new matter.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/  
Examiner, Art Unit 1645

/Robert B Mondesi/  
Supervisory Patent Examiner,  
Art Unit 1645